REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed June 13, 2008 and entry of the present amendment is requested because Applicant respectfully submits that the Amendment places the application in condition for allowance or in better form for consideration on appeal.

Claims 1-15, 23-34 remain pending with only claim 2 currently amended. Applicant would like to point out that claim 25 was amended in Applicant's previous response, although the status indicator of claim 25 did not specify "currently amended." The status of claim 25 is now identified as "previously amended" and reflects the amendments made in Applicant's previous response.

In the Final Office Action, claims 1, 2, and 29 were objected to. In addition, claims 1, 23, 24, and 29 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. US 6,682,556 ("the Ischinger reference"). Finally, claims 1, 7-14, 23-31, and 33-34 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,749,890 ("the Shaknovich reference") in view of U.S. Patent No. 6,572,612 ("the Stewart et al. reference"), claim 15 was rejected under 35 U.S.C. § 103(a) as unpatentable over as unpatentable over the Shaknovich reference in view of the Stewart et al. reference, and further in view of U.S. Patent No. 6,766,186 ("the Hoyns et al. reference"), claim 32 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Shaknovich reference in view of the Stewart et al. reference in view of U.S. Patent No. 5,702,418 ("the Ravenscroft reference"), and claims 2-6 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Ischinger reference in view of U.S. Patent No. 6,589,214 ("the McGuckin et al. reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the objections to the claims, Applicant submits that claims 1, 2, and 29 are clear as originally presented in that the interventional device is not being claimed but the structure and function is recited of the recited locator relative to an interventional device when the interventional device is affixed to the sheath. By contrast, claim 34 was added in Applicant's previous response to positively claim an interventional device. However, to further clarify the claims, claim 2 has been amended to recite a fastener for affixing the sheath to ***an*** interventional device. Accordingly, for these reasons, Applicant believes that the claim objections should be withdrawn.

With respect to the § 102(b) rejections, the Ischinger reference discloses a balloon catheter that includes a first guidewire channel 16 that extends to the distal end 10 of the catheter beyond the balloon, and a second guidewire channel 14 with a distal exit 11 located adjacent the balloon. Col. 2, lines 56-63, col. 3, lines 10-13; FIGS. 1A, 2A. During use, a first guidewire 12 is placed in the target sidebranch artery and a second guidewire 15 is placed in the main artery. Col. 3, lines 59-63. The first guidewire 12 is threaded into the first channel 16, the second guidewire 15 is threaded into the second channel 14, and the catheter is advanced over the guidewires 12, 15 until the distal exit 11 of the second channel 14 reaches the bifurcation and prohibits further advancement. Col. 3, line 64 through col. 4, line 5. Alternatively, the second guidewire 14 may be preloaded in the second channel 14 and advanced through the distal end 11 once the catheter is inside the patient. Col. 4, lines 5-12. The feature 100 shown in FIGS. 2A, 4A, and 4B is merely described in the Ischinger reference as a pig-tail shape tip that optionally

may be provided on the second guidewire 15. Col. 4, lines 29-34. The balloon catheter may be used to deliver a stent 40, 90 mounted on the balloon beyond the distal exit 11.

Turning to the present claims, claim 1 recites an apparatus for locating an interventional device relative to the ostium of a branch vessel that includes a sheath having proximal and distal ends, and a lumen extending therebetween, the sheath adapted to be affixed to an interventional device; and an ostial locator wire slidably disposed within the sheath, the ostial locator wire having a distal region initially provided in a retracted configuration within the lumen and that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen, the sheath being advanceable with the distal region in the expanded configuration to position the interventional device relative to the ostium, the ostial locator wire and sheath being removable after positioning the interventional device.

The Ischinger reference does not disclose, teach, or suggest an ostial locator wire having a distal region initially provided in a retracted configuration within a lumen of a sheath and that assumes an expanded configuration when extended from the sheath such that the distal region partially encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen. Although the Ischinger reference discloses a second guidewire 15 that may advanced from a distal exit 11 of a second channel 14 and may include a pig tail tip 100, the guidewire 15 does not and cannot ***partially encircle*** an interventional device. Specifically, neither the guidewire 15 nor the pig tail tip 100 encircles the stent 40, 90 disclosed in the Ischinger reference. For this reason,

claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Ischinger reference.

For similar reasons, claims 23 and 29 are also neither anticipated by nor otherwise obvious over the Ischinger reference. Claim 23 also recites an ostial locator that assumes an expanded configuration when extended from the distal end of a sheath and ***partially encircles*** and is spaced apart from a stent, which is not taught or suggested by the Ischinger reference, as explained above.

Similarly, claim 29 recites that the ostial locator assumes an expanded configuration when extended from the distal end of the sheath such that the distal region ***partially encircles*** an interventional device disposed beyond the sheath distal end. In addition, claim 29 further recites that the distal region assumes a shape in the expanded configuration ***that is flattened out axially when the sheath is advanced into an ostium***, thereby providing tactile feedback regarding the position of the distal region. No structure of the Ischinger device is flattened out axially when the sheath is advanced into an ostium, nor is any structure capable of being flattened, as claimed. For example, as clearly shown in FIGS. 4A and 4B of the Ischinger reference, the pig tail 100 is never flattened during use. For this additional reason, claim 29 and its dependent claims are neither anticipated by nor otherwise obvious over the Ischinger reference.

The other cited references fail to disclose, teach, or suggest such an ostial locator, as explained further below. Accordingly, claims 1, 23, and 29 and their dependent claims are not obvious even if the other cited references could somehow be properly combined with the Ischinger reference (which Applicant does not concede).

Turning to the rejections based on the combination of the Shaknovich and Stewart et al. references, the Shaknovich reference discloses an ostial stent delivery system or "shuttle" (1) that includes a catheter (4) having at its distal end a deployment segment (2) including a forward break segment (3) and an expandable segment (5) on which a stent (6) is mounted. Col. 4, lines 50-56. The break segment (3) may be a balloon (3E, 3F), a Nitinol wire loop (7), or a pair of articulated wires (8) within a membrane. See FIGS. 3-5, col. 4, line 57 through col. 5, line 7.

During use, the shuttle (1) is advanced over a guidewire 14 through a guiding catheter 16 into a target artery (10) distal to an ostial lesion (9). Col. 5, lines 33-36; FIG. 9. The guiding catheter 16 and then the shuttle (1) are withdrawn from the target artery (10), and the break segment is activated, i.e., expanded, as shown in FIGS. 10-12. Col. 5, lines 37-50. The deployment segment (2) is then advanced until the expanded break segment comes to a stop against the wall of the parent vessel (15). Col. 5, lines 51-55; FIG. 13. The stent may then be expanded using an ancillary balloon catheter to expand the deployment segment or an expandable portion over which the stent is mounted is expanded to expand the stent in the target artery. Col. 8, lines 55-61, col. 10, lines 9-15.

With respect to claim 1, the Shaknovich reference fails to disclose, teach, or suggest an ostial locator wire slidably disposed within the sheath, the ostial locator wire having a distal region initially provided in a retracted configuration within the lumen and that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen, the sheath being advanceable with the distal region in the expanded configuration to position the

interventional device relative to the ostium, the ostial locator wire and sheath being removable after positioning the interventional device.

In particular, the Shaknovich reference does not teach or suggest a locator that is initially provided in a retracted configuration within a lumen of a sheath and that ***assumes an expanded configuration when extended*** from the sheath. Instead, the Shaknovich reference merely discloses a break segment that is activated to expand and collapse, e.g., by inflating a balloon or expanding wires within a membrane. Further, the Shaknovich break segment does not ***partially encircle*** an interventional device affixed to the sheath. In contrast, the Shaknovich break segment is expanded adjacent, i.e., proximal to, a stent to help position the stent within the target artery. Thus, the Shaknovich reference is not deficient merely because it fails to disclose a wire, as concluded on page 4 of the Final Office Action. Instead, the Shaknovich reference also fails to disclose, teach, or suggest the configuration and mode of expansion of the claimed locator wire.

The Stewart et al. reference fails to provide any additional teaching or suggestion that may be properly combined with the Shaknovich reference to render the present claims obvious. The Stewart et al. reference discloses a catheter assembly 190 for treatment of cardiac arrhythmia that includes a catheter body 192 and a locating device 196 that are slidably deployable from a guide catheter or sheath 198. Col. 12, lines 32-37. The catheter body 192 includes electrodes 194 for ablating tissue and the locating device 196 include mapping electrodes 194. Col. 12, lines 58-64. The catheter body 192 is virtually identical to catheter body 62, shown in FIG. 3A, which is intended to be disposed about a pulmonary vein ostium to ablate tissue surrounding the ostium. Col. 9, lines 11-30. col. 12, lines 42-48.

Thus, the Stewart et al. catheter assembly 190 is intended for a completely different purpose than the Shaknovich shuttle (1). The Stewart et al. catheter body 192 is not intended to position an interventional device within a target branch artery, but is intended to position ablation electrodes around an ostium ***outside*** a pulmonary vein. Therefore, it would not be obvious to substitute the Stewart et al. catheter body 192 for the Shaknovich break segment (3).

Further, even if the references could somehow be properly combined, the result would be a configuration in which the Stewart et al. catheter 192 would be deployable from the distal end of the Shaknovich shuttle, i.e., beyond the stent (6). The Stewart et al. reference fails to teach or suggest how the catheter body 192 could be deployed in the location of the Shaknovich break segment in order to allow the catheter body 192 to somehow be deployed to partially encircle the stent (6). The Stewart et al. catheter body 192 is incapable of being deployed from a side of the Shaknovich shuttle without substantial modification, which be necessary to allow the catheter body 192 to surround the stent (6). The Shaknovich reference also fails to disclose, teach, or suggest how a locator could be deployed from the location of the break segment (3) such that the locator partially surrounds the stent (6). Therefore, even if the references could be properly combined (which Applicant disputes for the reasons given above), the result is not the subject matter of claim 1, but a catheter body that is expanded beyond a stent on a catheter. Accordingly, for these reasons, claim 1 and its dependent claims are not obvious over the cited references.

For similar reasons, claims 23 and 29 are also not obvious over the Shaknovich and Stewart et al. references, even if somehow properly combined with one another. Further, none of the cited references teaches or suggests a locator that assumes a shape in the expanded configuration ***that is flattened out axially when the sheath is advanced into an ostium***, as

recited in claim 29. Neither of the Shaknovich and Stewart et al. references teaches or suggests an expandable locator that is flattened to facilitate with positioning and/or provide tactile feedback to a user, e.g. as explained on pages 10-11 of Applicant's previous response. For this additional reason, claim 29 and its dependent claims are not obvious over the cited references.

Finally, none of the other cited references discloses, teaches, or suggests the features that are wholly absent from the Shaknovich and Stewart et al. references. Accordingly, the present claims are obvious even if the other cited references could be properly combined with the Shaknovich and Stewart et al. references (which Applicant does not concede).

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
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